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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/757,202      | 01/09/2001  | Robert J. Miller     | GC-10.6-CON         | 8824             |

24536 7590 05/28/2003

GENZYME CORPORATION  
LEGAL DEPARTMENT  
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FRAMINGHAM, MA 01701-9322

[REDACTED] EXAMINER

WHITE, EVERETT NMN

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1623

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DATE MAILED: 05/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |               |
|------------------------------|-----------------|---------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s)  |
|                              | 09/757,202      | MILLER ET AL. |
|                              | Examiner        | Art Unit      |
|                              | EVERETT WHITE   | 1623          |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 March 2003.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 15-30 and 60-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 15-30 and 60-76 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                      | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 . | 6) <input type="checkbox"/> Other: _____                                     |

## DETAILED ACTION

1. The response filed March 28, 2003 has been received, entered and carefully considered. The response affects the instant application accordingly:
  - (A) Comments regarding Office Action have been provided drawn to
    - (a) Obviousness-type double patenting rejection, rendered moot by new ground of rejection over newly cited US Patent.
2. Claims 15-30 and 60-76 are pending in the case.
3. The text of those sections of title 35, U. S. Code not included in this action can be found in a prior Office action.

### ***Claim Objections***

4. Claim 15 is objected to because of the following informalities: In Claim 15, line 7, the term "groups" should be changed to - - group -. Appropriate correction is required.

### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 15-30 and 60-76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-21 of U.S.

Patent No. 5,760,200 in view of Balazs et al (US Patent No. 4,713,448). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application and U.S. Pat. 5,760,200 set forth claims directed to a method of making a water insoluble biocompatible composition comprising combining in an aqueous mixture a polyanionic polysaccharide, nucleophile, and an activating agent under conditions sufficient to form said composition. Examples of the polyanionic polysaccharides, nucleophiles, and activating agents that are used in the instant application are analogous to the polyanionic polysaccharides, nucleophiles, and activating agents used in U.S. Patent No. 5,760,200. The claims of the instant application differ from the claims of U.S. Patent No. 5,760,200 by further including a modifying agent that causes the formation of a new active carbonyl group on said polyanionic polysaccharide. However, the Balazs et al patent shows that the formation of carbonyl group on a polyanionic polysaccharide is well known in the art. Balazs et al discloses a process that involves treating hyaluronic acid, a polyanionic polysaccharide, with an aldehyde such as formaldehyde to produce a hyaluronic acid comprising an aldehyde (such as formaldehyde) covalently attached directly to the hyaluronic acid (see column 7, lines 39-42). It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a biocompatible composition by combining a polyanionic polysaccharide, a nucleophile, and an activating agent of US Patent No. 5,760,200 and to use a modifying compound such as an aldehyde for modifying the polyanionic polysaccharide in view of the recognition in the art, as evidenced by the Balazs et al patent, that aldehydes are effective compounds for the formation of carbonyl groups attached directly onto polyanionic polysaccharides such as hyaluronic acid.

7. Claims 15-30 and 60-76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,174,999. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application and U.S. Pat. 6,174,999 set forth claims directed to a method of making a water insoluble

biocompatible composition comprising combining in an aqueous mixture a polyanionic polysaccharide, nucleophile, and an activating agent under conditions sufficient to form said composition. Examples of the polyanionic polysaccharides, nucleophiles, and activating agents that are used in the instant application are analogous to the polyanionic polysaccharides, nucleophiles, and activating agents used in U.S. Patent No. 6,174,999. The claims of the instant application differ from the claims of U.S. Patent No. 6,174,999 by further including a modifying agent. However, the Balazs et al patent shows that the formation of carbonyl group on a polyanionic polysaccharide is well known in the art. Balazs et al discloses a process that involves treating hyaluronic acid, a polyanionic polysaccharide, with an aldehyde such as formaldehyde to produce a hyaluronic acid comprising an aldehyde (such as formaldehyde) covalently attached directly to the hyaluronic acid (see column 7, lines 39-42). It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a biocompatible composition by combining a polyanionic polysaccharide, a nucleophile, and an activating agent of US Patent No. 5,760,200 and to use a modifying compound such as an aldehyde for modifying the polyanionic polysaccharide in view of the recognition in the art, as evidenced by the Balazs et al patent, that aldehydes are effective compounds for the formation of carbonyl groups attached directly onto polyanionic polysaccharides such as hyaluronic acid.

### ***Summary***

8. All the claims are rejected.

### ***Examiner's Telephone Number, Fax Number, and Other Information***

9. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-

4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

*E. White*  
E. White

*James O. Wilson*  
James O. Wilson  
Supervisory Primary Examiner  
Technology Center 1600